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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,032	12/06/2000	Bryan Paul Morgan	WN/KH/JJ/WCM	7516

7590 02/28/2002

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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/28/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,032	MORGAN ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-12 and 27, drawn to cells or tissue and methods of using.

Group II, claim 13-16, 28 and 29, drawn to a transgenic animal and method of making.

Group III, claims 17, 20, 26 and 30 drawn to CD59 DNA, probes and primers.

Group IV, claims 18 drawn to DAF DNA.

Group V, claim 19, drawn to CD59 RNA.

Group VI, claims 21 and 22, drawn to CD59 protein.

Group VII, claims 23 and 24, drawn to DAF protein.

Group VIII, claim 25, drawn to an anti-CD59 antibody.

Group IX, claim 25, drawn to an anti-DAF antibody.

Group X, claim 28, drawn to a method of gene therapy.

Group XI, claims 31-33, drawn to a method of increasing resistance to complement attack in transplants using various chemicals and conditions.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I and II are patentably distinct because the cells/tissues are used for transplantation while the transgenic is used as an in vivo model for complement studies. The cell/tissue does not require the transgenic as they can be made in vitro.

Groups I and III or IV are patentably distinct because the cells/tissues are used for transplantation while the DNA can be used as a primer or probe. The cells/tissues of claims 1-13 do not require the DNA.

Groups I and V are patentably distinct because the cells/tissues are used for transplantation while the RNA is used for blocking transcription (antisense). The cells/tissues do not require the RNA and the RNA does not require the cells/tissues.

Groups I and VI or VII are patentably distinct because the cells/tissues are used for transplantation while the CD59 or DAF protein can be used to isolate antibodies. The cells/tissues do not require the proteins and the proteins does not require the cells/tissue.

Groups I and VIII or IX are patentably distinct because the cells/tissues are used for transplantation while the antibodies can be used to isolate proteins. The cells/tissues do not require antibodies and the antibodies does not require the cells/tissue.

Groups I and X are patentably distinct because the cells/tissue do not have to be transfected and can be made by treating the cells with compounds Group XI.

Groups I and XI are related as a product and a method of making the product. However, the product can be made by methods other than those in Group XI, e.g. by making a transgenic animal. Therefore, the inventions are not linked by the same inventive concept.

Groups II and III or IV are related as a product and a method of using the product. However, the product can be made by methods other than those in Group III, e.g. by administering a compound to the cell (Group XI). Therefore, the inventions are not linked by the same inventive concept.

Groups II and V are not related by any inventive concept. The trasngenics are not made using RNA and the RNA does not require transgenics.

Groups II and VI or VII are not related by any inventive concept. The transgenics are not made using protein and the protein does not require the transgenics.

Groups II and VIII or IX are not related by any inventive concept. The transgenics are not made using antibodies and the antibodies do not require the transgenics.

Groups II and X are not related because the trasngenics do not have to be used for gene therapy; they can be an in vivo model for complement activity. In addition, gene therapy does not require the transgenics, e.g. transfecting cells *in vitro* and administering the cells to a host.

Groups II and XI are not related because the method of making a transgenic does not require administering the various chemicals and conditions to the cells/tissues in Group XI and because the method of Group XI does not require the transgenics.

Groups III and IV are patentably distinct because CD59 and DEF are structurally and functionally distinct; therefore, the DNA encoding CD59 and DEF are structurally and functionally distinct.

Groups III and V are patentably distinct because CD59 DNA can be used as a probe while CD59 can be used as antisense to prevent transcription or CD59.

Groups III or IV and VI or VII are patentably distinct because DNA can be used as a probe while the protein can be used to isolate antibodies.

Groups III or IV and VIII or IX are patentably distinct because DNA can be used as a probe while the antibodies can be used to isolate proteins.

Groups III or IV and X are related as a product and method of using. However the DNA can used as a probe or to make transgenics and is not limited to use in gene therapy.

Groups III or IV and XI are not related because the DNA does not require the method and the method does not require the DNA.

Groups IV and V are not related because they relate to structurally and functionally distinct proteins and because DNA and RNA have different functions (probe vs. antisense).

Groups V and VI or VII are patentably distinct because RNA can be used as antisense while the protein can be used to isolate antibodies.

Groups V and VIII or IX are patentably distinct because RNA can be used as antisense while the antibodies can be used to isolate proteins.

Groups V and X are patentably distinct because the RNA can be used as antisense while the method of gene therapy is used to treat disease.

Groups V and XI are not related because the RNA does not require the method and the method does not require the RNA.

Groups VI and VII are patentably distinct because CD59 and DEF are structurally and functionally distinct. The search required for CD59 is not required for DEF and vice versa. The burden required to search both would be undue because of the sequence searches.

Groups VI or VII and VIII or IX patentably distinct because the proteins can be used in the complement cascade while the antibodies can be used to isolate proteins.

Groups VI or VII and X are patentably distinct because the proteins can be used to isolate antibodies while the method of gene therapy is used to treat disease.

Groups VI or VII and XI are not related because the proteins do not require the method and the method does not require the proteins.

Groups VIII and IX are patentably distinct because antibodies against CD59 and DEF are structurally and functionally distinct. The search required for an antibody against CD59 is not required for an antibody against DEF and vice versa. The burden required to search both would be undue.

Groups VIII or IX and X are patentably distinct because the antibodies can be used to isolate protein while the method of gene therapy requires DNA.

Groups VIII or IX and XI are not related because the antibodies do not require the method and the method does not require the antibodies.

Groups X and XI are not related because the method of gene therapy requires DNA which is not required for the method of Group XI and because the method of Group XI requires compounds which are not required for the method of gene therapy.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: CD59, MCP, DAF, HRF and CR1.

Groups I, II and X are generic to CD59, MCP, DAF, HRF and CR1. These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each proteins has a patentably distinct structure and function. The search required for one protein would not be required for any other protein. Specifically, if a search were based upon the sequence of the various patentably distinct species listed above, such a search would be undue.

Claim 28 is generic to gene therapy and making transgenic animals to obtain transplantation tissue. These inventions are patentably distinct for reasons set forth above comparing Groups II and X.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent

Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The description of Fig. 2 is missing a SEQ ID NO for the nucleic acid sequence.** Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing." Applicant is requested to return a copy of the attached Notice to Comply with the reply. Failure to fully comply with the sequence rules in response to the instant office action will be considered non-responsive.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL C. WILSON
PATENT EXAMINER